## Department of SHALYA TANTRA

<table>
<thead>
<tr>
<th>Roll No</th>
<th>Scholar</th>
<th>Title Of Synopsis</th>
<th>Guide</th>
<th>Co-Guide</th>
</tr>
</thead>
<tbody>
<tr>
<td>35.</td>
<td>Dr. Anuja Nair N.J</td>
<td>“Uncontrolled Single Armed Clinical Study In The Management Of Non-Toxic Goitre By Triphaladyoguggulu And Sarshapadipralepa”</td>
<td>Dr. Rabinarayan Tripathy</td>
<td>Dr. Shaithya Raj.</td>
</tr>
<tr>
<td>36.</td>
<td>Dr. Neelima Sherly John</td>
<td>“Open Label Clinical Study To Evaluate The Comparative Effectiveness Of Gunavathi Varthi And Nishadi Taila In Low Anal Fistula.”</td>
<td>Dr. Rabinarayan Tripathy.</td>
<td>Dr. Shaithya Raj.</td>
</tr>
<tr>
<td>37.</td>
<td>Dr. Sreedevi V</td>
<td>“Uncontrolled Single Armed Clinical Study In The Management Of Fissure-In-Ano By Durvaadi Kera Taila”</td>
<td>Dr. Rabinarayan Tripathy.</td>
<td>Dr. Shaithya Raj.</td>
</tr>
<tr>
<td>38.</td>
<td>Dr. P. Suresh</td>
<td>“Open Label Case Controlled Clinical Study To Evaluate The Effectiveness Of Nyagrodhadi Gana In Bhagna Sandhaana.”</td>
<td>Dr. G.S.Raju</td>
<td>Dr. Rabinarayan Tripathy.</td>
</tr>
</tbody>
</table>
PROFORMA FOR REGISTRATION OF SUBJECT FOR DISSERTATION FOR
AYURVEDA VACHASPATI M.S (Ay) IN SHALYATANTRA

“UNCONTROLLED SINGLE ARMED CLINICAL STUDY IN THE
MANAGEMENT OF NON-TOXIC GOITRE BY TRIPHALADYO-GUGGULU&
SARSHAPADI PRALEPA”

BY
ANUJA NAIR. N.J

GUIDE
Prof.Dr. RABINARAYAN TRIPATHY. MS (Ay)

CO-GUIDE
Dr. SHAITHYA RAJ. MS (Ay)
LECTURER

DEPARTMENT OF POST GRADUATE STUDIES IN SHALYATANTRA
AMRITA SCHOOL OF AYURVEDA, VALLIKKAVU
CLAPPANA P.O, KOLLAM, KERALA

SESSION - 2013-14
From
Dr. ANUJA NAIR N.J
I Year M. S. (Ay) Scholar
Department of Post Graduate Studies in Shalyatantra
Amrita School of Ayurveda, Vallikkavu, Clappana P.O, Kollam, Kerala.

To
The Registrar
Amrita Viswa Vidyapeetham, Ettimadai, Coimbatore, Tamilnadu

Through - The Principal and Head of Department of P.G. studies in Shalyatantra, Amrita School of Ayurveda, Vallikkavu, Clappana P.O, Kollam, Kerala

Subject: Submission of Completed Proforma for Registration of Synopsis of Dissertation.

Respected Sir,

I request you to kindly register the below mentioned subject against my name for submission of the dissertation to the Amrita Viswa Vidyapeetham, Coimbatore, Tamilnadu, as partial fulfillment of M.S (Ay) in Shalyatantra.

THE TITLE OF DISSERTATION

“UNCONTROLLED SINGLE ARMED CLINICAL STUDY IN THE MANAGEMENT OF NON-TOXIC GOITRE BY TRIPHALADYO-GUGULU & SARSHAPADI PRALEPA”

I am enclosing completed proforma for registration of subject of dissertation.

Thanking You.

Yours faithfully,

(Dr. ANUJA NAIR N.J)

Date:
Place: Vallikkavu
1. BRIEF RESUME OF THE INTENDED WORK.

Goitre is defined as diffuse enlargement of the thyroid gland \(^{(1)}\). Goitre has ceased to be a major problem in many developed countries and it continues to be a serious health problem in many Third World Countries. The magnitude of the problem in India is far greater than what had been in the 1960s, when it was estimated that about 9 million people were affected by goitre. Now it is estimated that more than 71 million people are suffering from goitre and other iodine deficiency disorders in the country \(^{(2)}\). Galaganda is a similar condition explained in the classical texts of Ayurveda. It is told as a mamsa pradoshajavikara \(^{(3)}\) presented with glandular swelling, produced by the vitiation of vata and kapha accumulated & localized at neck (Gala) along with medas \(^{(4,5)}\).Goitre is often treated by anti thyroid drugs, radioactive iodine therapy and surgery, but successfully by subtotal thyroidectomy, where most of the thyroid gland is removed. Management of Galaganda is documented in ancient compendium like Brihatrayee & Laghutrayee. Triphaladyo-guggulu is mentioned in Yogaratnakara \(^{(6)}\) which is found effective in management of Gandamala and Galagranthi. Sarshapadipralepa is also highly praised in the management of Galaganda as a local application in Bhavaprakasa \(^{(7)}\), Bhaishajyaratnavali \(^{(8)}\) and Chakradatta \(^{(9)}\) which can dissolve serious types of Galaganda, Granthi and Gandamala.

I. NEED FOR THE STUDY

- Goitre is most common now a day in every part of the world. Often it may be associated with complications like difficulty in breathing, swallowing, change in voice etc and inevitably with some cosmetic problems.
- Modern management measures have their own side effects and most of them are very costly. Surgical removal may lead to an underactive thyroid and medicinal management like use of Thyroid hormone pills needs long term therapy.
- Ayurveda can offer safe and effective management for Galaganda, without producing any side effects or complications.
- The etiopathogenesis of Galaganda and Gandamala is same. Since Triphaladyo-guggulu is mentioned in the treatment of Gandamala, hence the effect of Triphaladyo-guggulu on Galaganda has to be evaluated.
- According to Ayurvedic classical texts Sarshapadipralepa plays an important role in management of Galaganda, as it can dissolve even serious types of Goitre.
- Sarshapadipralepa is in the form lepa. So as an external application, it is very easy to use.
Both the internal and external medication contains a few indigenous drugs which are easily available and cost effective so that it is within the reach of poor people.

II. REVIEW OF LITERATURE:

- The review of literatures includes thorough screening of classical Ayurvedic literature, Modern textbooks, Journals, internet sources etc.

**Previous work done:**

1. Badaruddin.- Clinical trial of Yashtimadhu in the cases of Thyrotoxicosis, Faculty of Ayurveda, I M S, BHU 1979
3. Rakesh Kumar- Studies on management of different types of Goitre by Ayurvedic compounds, Faculty of Ayurveda, I M S, BHU, 1988

III. AIMS AND OBJECTIVES OF THE STUDY:

- To evaluate the clinical efficacy of Triphaladyo-guggulu & Sarshapadipralepa in the management of Non Toxic Goitre.
- To evaluate the efficacy of Triphaladyo-guggulu & Sarshapadipralepa on TSH value.

2. MATERIALS AND METHODS:

I. SOURCES OF DATA:

Patients suffering from Non Toxic Goitre will be selected from the OPD & IPD of Amrita Ayurveda Hospital, Vallikkavu, Kollam and other nearby hospitals and clinics. For inclusion and exclusion of patients under the study the pathological laboratory attached to the hospital will be used.

II. MATERIALS REQUIRED FOR THE STUDY:

Materials required for the present study includes one internal medicine Triphaladyo-guggulu & one external medicine Sarshapadipralepa. Ingredients for the preparation of the drug will be collected from the local market. Triphaladyo-guggulu will be prepared according to
textual reference of Yogaratnakara & Sarshapadipralepa according to the textual reference of Bhaishajyaratnavali under the supervision of Bhaishajya & Dravyaguna Departments.

**DRUG REVIEW**

**Triphaladyo-guggulu:**

Guggulu is purified in triphalaquatha in dolayantra and fried in ghee & powdered. The fine powder of Triphala, Trikatu, Kanchanaratvak and Guggulu is pounded well in a mortar and ground along with Honey and made into the form of gutika and dried.

Triphaladyo-guggulu contains the following ingredients.

<table>
<thead>
<tr>
<th>Sans. Name</th>
<th>Bot. Name</th>
<th>Family</th>
<th>Rasa</th>
<th>Guna</th>
<th>Veerya</th>
<th>Vipaka</th>
<th>Karma</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vibheetaki</td>
<td><em>Terminalia bellerica</em></td>
<td>Combretaceae</td>
<td>Kashaya Tiktha</td>
<td>Laghu,</td>
<td>Ushna</td>
<td>Madhura</td>
<td>Kantha rogagna</td>
</tr>
<tr>
<td>Amalaki</td>
<td><em>Emblica officinalis</em></td>
<td>Euphorbiaceae</td>
<td>Amla Kashaya Madura</td>
<td>Laghu,</td>
<td>Seetha</td>
<td>Madhura</td>
<td>Tridosahara</td>
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<tr>
<td>Nagara</td>
<td><em>Zingiber officinale</em></td>
<td>Zingiberaceae</td>
<td>Katu</td>
<td>Guru</td>
<td>Ushna</td>
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<td>Kantha rogagna</td>
</tr>
<tr>
<td>Pippali</td>
<td><em>Piper longum</em></td>
<td>Piperaceae</td>
<td>Katu</td>
<td>Laghu Tiksha</td>
<td>Ushna</td>
<td>Katu</td>
<td>Kaphahara Medohara</td>
</tr>
<tr>
<td>Maricha</td>
<td><em>Piper nigrum</em></td>
<td>Piperaceae</td>
<td>Katu</td>
<td>Laghu Tiksha</td>
<td>Ushna</td>
<td>Katu</td>
<td>Kapha vatahara</td>
</tr>
<tr>
<td>Kanchanara</td>
<td><em>Bauhinia variegata</em></td>
<td>Caesalpiniaceae</td>
<td>Kashaya</td>
<td>Laghu</td>
<td>Seetha</td>
<td>Katu</td>
<td>Gandamalagna</td>
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<tr>
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<td><em>Commiphora mukul</em></td>
<td>Burseraceae</td>
<td>Thiktha Kashaya</td>
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<td>Ushna</td>
<td>Katu</td>
<td>Sophagna</td>
</tr>
<tr>
<td>Kshaudra</td>
<td></td>
<td></td>
<td>Kashaya Madhura</td>
<td>Guru</td>
<td>Ushna</td>
<td>Katu</td>
<td>Chedya</td>
</tr>
</tbody>
</table>

**Sarshapadi pralepa:** Seeds of Sarshapa, Sigru, Sana, Athasi, Yava and Moolaka is made into powder and triturated along with sour butter-milk. This mixture is applied as lepa.

Sarshapadipralepa contains the following ingredients:

<table>
<thead>
<tr>
<th>Sanskrit Name</th>
<th>Botanical Name</th>
<th>Family</th>
<th>Rasa</th>
<th>Guna</th>
<th>Veerya</th>
<th>Vipaka</th>
<th>Karma</th>
</tr>
</thead>
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<td>Katu Tikta</td>
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<td>Ushna</td>
<td>Katu</td>
<td>Sophagna</td>
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<td>Laghu</td>
<td>Ushna</td>
<td>Katu</td>
<td>Sophagna</td>
</tr>
<tr>
<td>Plant</td>
<td>Family</td>
<td>Method</td>
<td>Property</td>
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</tr>
<tr>
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<td>Tikta</td>
<td>Tikshna</td>
<td>Ushna</td>
<td>Katu</td>
<td>Kanthorgagna</td>
<td></td>
</tr>
<tr>
<td>Athasi</td>
<td>Linaceae</td>
<td>Tikta</td>
<td>Madhura</td>
<td>Guru</td>
<td>Pichila</td>
<td>Ushna</td>
<td>Katu</td>
</tr>
<tr>
<td>Yava</td>
<td>Poaceae</td>
<td>Kashaya</td>
<td>Madhura</td>
<td>Guru</td>
<td>Ruksha</td>
<td>Seetha</td>
<td>Katu</td>
</tr>
<tr>
<td>Moolaka</td>
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<td>Tikta</td>
<td>Laghu</td>
<td>Ruksha</td>
<td>Ushna</td>
<td>Katu</td>
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<tr>
<td>Takra</td>
<td></td>
<td>Amla</td>
<td>Kashaya</td>
<td>Laghu</td>
<td>Ushna</td>
<td>Madura</td>
<td>Sophagna</td>
</tr>
</tbody>
</table>

**i) METHODS OF COLLECTION OF DATA:**

1. **SAMPLE**

Thirty patients suffering from Non Toxic Goitre will be selected on the basis of simple random sampling (SRS).

2. **INCLUSION CRITERIA**

   i) Patients between the ages of 15-60 years, irrespective of sex.
   
   ii) Patients suffering from non-toxic goitre including colloid goitre, diffuse goitre, non-toxic multi nodular goitre, and non-toxic single nodular goitre

3. **EXCLUSION CRITERIA:**

   i) Patients below 15 years & above 60 years.
   
   ii) Patients having Toxic-goitre, Neoplastic goitre, Thyroiditis, Physiological goitre.
   
   iii) Patients having difficulty in swallowing, breathing and change in voice.
   
   iv) Patients having other systemic pathology (TB, DM, HIV, HBsAg, etc)
   
   v) Patients under medications for thyroid abnormalities.

**ii. PROCEDURE AND DESIGN OF THE STUDY**

Thirty patients of Non Toxic Goitre will be selected in a systematic random sampling procedure according to the inclusion and exclusion criteria. Patients should be informed about the package of treatment for the clinical trial and the consent will be taken. After getting consent from the patients / guardian, they will be registered under Trial. The ingredients for the preparation of the trial drug will be collected from local market and will be prepared under the guidance of Bhaishajya & Dravyaguna departments. Patients will be given Triphaladyo-guggulu internally & Sarshapadipralepa externally.
Internally – Triphaladyoguggulu will be given to each patient in a dose of 4gm (2 tablets 2 gm each) three times a day (8hrly) depending upon the age of the patient with anupana of luke warm water

Externally – Sarshapadipralepa, will be applied in approximately 0.5cm (1/4angula) thickness, in the anterior part of neck, once daily in the morning for 3months. Pralepa will be wiped off before drying depending upon the climatic conditions.

All the patients will be advised to take same type of food and to maintain same life style as prescribed. The treatment duration will be 3 months in total. Assessment of clinical sign/ symptom and of investigations will be done on 0day, 30th day & 60th day, 90th day and will be recorded in specially prepared case sheets.

4. ASSESSMENT CRITERIA -
   i) Swelling
   ii) TSH value
   iii) Size of lobe and isthmus

Investigations required.
   1. Thyroid Function Test
   2. Neck USG
   3. FNAC(if required)
   4. Routine Blood, Urine, Stool examinations in order to rule out systemic pathologies(if necessary)

5. STATISTICAL METHODS
   Paired T Test, or Chi-square Test will be adopted for Statistical analysis.

SINGLE GROUP DESIGN

\[
\begin{array}{c}
T_G \\
BT \\
V_S \\
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\end{array}
\]
The efficacy of trial drug will be evaluated

3. Does the study require any investigations or interventions to be conducted on patients, healthy volunteers, cadaver or animal? If so, please describe briefly
   Yes, Study requires investigations in Goitre patients using medicated drugs. No healthy volunteers, cadaver or animal experiments will be conducted.

4. Has ethical clearance been obtained from your institution in case of (human/animal)study? YES
5. LIST OF REFERENCES:

😊 😊 😊
Name of the researcher/ Scholar : ANUJA NAIR N.J

Signatures :

Name & designation of the guide : Dr. RABINARAYAN TRIPATHY, MS (Ay) 
PROFESSOR & HO D 
PG DEPARTMENT OF SHALYATANTRA.

Remarks of the Guide :

Signatures with official seal :

Name and designation of
 The Co-guide :
Dr. SHAITHYA RAJ, MS (Ay) 
LECTURER 
PG DEPARTMENT OF SHALYATANTRA

Signatures with official seal :

Name and designation of
Head of Department :
Dr. RABINARAYAN TRIPATHY, MS (Ay) 
PROFESSOR & HO D 
P G. DEPARTMENT OF SHALYATANTRA

Signatures with official seal :

Name & designation of
Head of Institution :
Dr. M.R. VASUDEVAN NAMPOOTHIRI, MD (Ay) 
PRINCIPAL, AMRITA SCHOOL OF AYURVEDA

Signatures with official seal:

TOP
PROFORMA FOR REGISTRATION OF SUBJECT FOR DISSERTATION FOR
AYURVEDA VACHASPATI, M S (Ay) IN SHALYATANTRA

“OPEN LABEL CLINICAL STUDY TO EVALUATE THE COMPARATIVE
EFFECTIVENESS OF GUNAVATI VARTI AND NISHADI TAILA IN LOW ANAL
FISTULA.”

BY
NEELIMA SHERLY JOHN

GUIDE
Prof. Dr. RABINARAYAN TRIPATHY. MS (Ay)

CO-GUIDE
Dr. SHAITHYA RAJ. MS (Ay); LECTURER

DEPARTMENT OF POST GRADUATE STUDIES IN SHALYATANTRA
AMRITA SCHOOL OF AYURVEDA, VALLIKKAVU, CLAPPANA P O ,
KOLLAM, KERALA

SESSION - 2013-2014
From,

Dr. NEELIMA SHERLY JOHN

I Year M. S. (Ay) Scholar,
Department of Post Graduate Studies in Shalyatantra
Amrita School of Ayurveda, Vallikkavu, Clappana P O, Kollam, Kerala.

To,

The Registrar, Amrita Viswa Vidyapeetham, Ettimadai, Coimbatore, Tamilnadu

Through - The Principal and Head of Department of P.G. studies in Shalyatantra, Amrita School of Ayurveda, Vallikkavu, Clappana P O Kollam, Kerala.

Subject: Submission of Completed Proforma for Registration of Synopsis of Dissertation.

Respected Sir,

I request you to kindly register the below mentioned subject against my name for the submission of the dissertation to the Amrita Viswa Vidyapeetham, Coimbatore as partial fulfillment of M.S. (Ay) in Shalyatantra.

THE TITLE OF DISSERTATION

“OPEN LABEL CLINICAL STUDY TO EVALUATE THE COMPARATIVE EFFECTIVENESS OF GUNAVATI VARTI AND NISHADI TAILA IN LOW ANAL FISTULA.”

I am enclosing completed Proforma for Registration of Subject of dissertation.

Thanking You,

Yours faithfully

(Dr. NEELIMA SHERLY JOHN)

Date: 28-05-2014

Place: Vallikkavu
1. BRIEF RESUME OF THE INTENDED WORK.

*Bhagandara* is enumerated under *Ashta Mahagada* & clinically co-related to Fistula-in-ano. It is a communicating tract lined by unhealthy granulation tissue; opens internally in the anal canal or rectum and superficially on the skin around the anus.

*Bhagandara* often becomes embarrassing due to pain, itching, and soiling of cloth because of its location, nature and notoriety in healing. In Modern medical science this condition is treated by fistulotomy and fistulectomy that need prolonged hospitalization and chances of recurrence are also common. Economically poor patients cannot undergo these surgical procedures because of its high cost. That is why so many patients with *Bhagandara* are looking forward to be treated by an alternative system of medicine.

The hypothesis postulated in relation to *Gunavati Varti* and *Nishadi Taila* is encouraging in the management of fistula-in-ano. Hence the study is proposed.

I. NEED FOR THE STUDY:

- Fistulectomy, the procedure where the complete removal of fistulous tract creates a wide open wound takes months together to heal up. It is also an invasive technique which needs general anaesthesia and use of higher antibiotics.
- Fistulotomy, where the fistulous tract is laid open also needs anaesthesia and often the healing may be incomplete and chances of further fistula are common.
- Both procedures are having high recurrence rate.
- *Ksharasutra* ligation being a standard procedure is also accompanied with intolerable pain, discharge, frequent change of *Ksharasutra* and a long period for healing.

To overcome these disadvantages in the present study; the procedures like *Taila prayoga* and *Varti prayoga* are proposed for trial.

II. REVIEW OF LITERATURE:-

- The review of literatures includes thorough screening of classical Ayurvedic literatures, Modern textbooks, Journals, internet sources etc.
- *Bhagandara Nidana, Lakshana and Chikitsa* as per Ayurveda classics.
- In *Nadivrana Chikitsa* mentioned as *Poorana* of medicated *Taila* will help in the faster healing of track (Su.Chi17/41 Dalhana).
- The detailed description of *Nishadi Taila Yoga (Bhagandara chikitsa)* Bhaishajyaratnavali (Chakradutta46/25).
The detailed description of Gunavati Varti as per Bhaishajya Ratnavali.8
The detailed description of Chiruvilwadi Kashaya as per Sahasrayoga.11
Fistula-in-ano as per modern science.

Previous work done
1. Sameer chaudhary-The effect of Padanakarma with Apamargadi lepa in the management of Bhagandara NKJAMC, Bidar, RGUHS, 2008
3. Shivaleela Mallappanavar - Clinical evaluation of Nishadi Taila Poorana with the standard Ksharasutra in the management of Bhagandara – RGUHS-2010
4. Renjith.R.Warier - A comparative clinical study on efficacy of Kasisadi Taila Poorana and Aragwadadi varthi in the management of Bhagandara (fistula-in-ano) RGUHS-2011

III. AIM AND OBJECTIVE OF THE STUDY:-
1. To evaluate the efficacy of Nishadi Taila in the management of Bhagandara.
2. To evaluate the efficacy of Gunavati Varti in the management of Bhagandara.
3. To compare the clinical efficacy of Nishadi Taila and Gunavati Varti in the management of Bhagandara.

2. MATERIALS AND METHODS:
   1. SOURCES OF DATA:-
      • Patient will be selected from the Shalyatantra OPD and IPD of Amrita Ayurveda hospital, other nearby hospitals and clinics, diagnosed as Bhagandara (Fistula-in-ano) and fulfilling the inclusion criteria.
      • After being scrutinized, patients will be registered under the present study.
      • Pathological laboratory attached to the hospital.
   2. MATERIALS REQUIRED FOR THE STUDY
      Material required for the present study is Nishadi Taila, Gunavati Varti and Chiruvilwadi Kashaya. It will be prepared in the pharmacy attached to college, according to the textual reference of Bhaishajyaratnavali & Chiruvilwadi kashaya according to Sahasrayoga under the direct supervision of Dravyaguna & Rasasastra department faculties in Amrita School of Ayurveda.

DRUG REVIEW:
Nishadi Taila7 - The Nishadi Taila will be prepared by Tila Taila taking as its base after making the Taila Murchana. The following ingredients will be mixed with Murchita taila as per the Tailapaka Vidhi.
The Gunavati Varti will be prepared by taking bees wax as the base with the following ingredients.

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<th>Bot. Name</th>
<th>Family</th>
<th>Rasa</th>
<th>Guna</th>
<th>Veerya</th>
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<td>Tikta,</td>
<td>Laghu</td>
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<td>Sindhu</td>
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<td>Nacl + Kcl</td>
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<td></td>
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<td>Vahni</td>
<td>Plumbago Roseae</td>
<td>Plumbagineae</td>
<td>Katu</td>
<td>Ushna</td>
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<td>Arsohara Sodha Hara</td>
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<tr>
<td>Vatsaka</td>
<td>Holorrhena</td>
<td>Apocynaceae</td>
<td>Tikta,</td>
<td>Laghu,</td>
<td>Seetha</td>
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<td>Ruksha</td>
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<td>Sesame Oil</td>
<td>Sesamum</td>
<td>Pedaliaceae</td>
<td>Madura</td>
<td>Guru</td>
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<td>Kashaya</td>
<td>Snighda</td>
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</tr>
</tbody>
</table>

2. **Gunavati Varti** – The *Gunavati Varti* will be prepared by taking bees wax as the base with the following ingredients.
i) METHODS OF COLLECTION OF DATA:-

1. SAMPLE-Forty patients will be selected from the recipients, who are suffering from fistula-in-ano and fulfilling the inclusion criteria, reporting to the Shalyatantra OP of Amrita Ayurveda hospital, according to simple random sampling.

2. INCLUSION CRITERIA

- Patients with the clinical features of Bhagandara (Fistula-in-ano) like soiling of cloth, presence of external opening near the anal canal, pain and discharge on and off,
- Age in between 20-60, irrespective of sex,
- Low anal fistula,
- Fistula tract measuring less than 3cm,
- Fistula with single external and single internal opening,

will be selected.

3. EXCLUSION CRITERIA:-

- Patients of age less than 20 and more than 60.
- High anal fistula,
- Multiple fistula,
- Trans sphincteric high anal fistula,
- Inter sphincteric high anal fistula,
- Extra sphincteric fistula,
- Fistula tract measuring more than 3 cm,
- Patients with Fistulous tracts secondary to some pathology such as Tuberculosis, Crohn’s disease, Actinomycosis,
- Pregnancy,
- HIV and HBsAg positive, uncontrolled Diabetes and with other systemic disorders will be excluded.

(ii) PROCEDURE AND DESIGN OF THE STUDY:

1. MATERIALS AND METHODS;
   i) Forty Bhagandara patients will be randomly selected according to the inclusion criteria. After proper case taking, investigations and examinations, probing will be performed to find out the length of fistulous tract. Then medicines will be administered in both groups.
   ii) Raw drugs for the preparation of Gunavati Varti, Nishadi Taila, Chiruvilwadi Kashaya will be collected from local market under the supervision of faculties of Dravyaguna Department of Amrita school of Ayurveda.

2. STUDY DESIGN:

Present study is a comparative clinical study, in which forty patients will be selected on the basis of simple random sampling (SRS) procedure & will be divided in 2 equal groups,

- **G1-Trial 1**: Patients will be treated with Nishadi Taila externally and Chiruvilwadi Kashaya internally.

- **G2-Trial 2**: Patients will be treated with Gunavati Varti externally and Chiruvilwadi Kashaya internally.

After treatment, the patients will be regularly observed. The changes will be noted in the specially prepared case sheet.

3. GROUPING

Forty patients will be selected and randomly categorized into two Groups as Group A (trial 1) and Group B (trial 2)

**Group A:**
- Sample size: 20 patients
- Drug: Nishadi taila externally and Chiruvilwadi Kashaya internally.
- Procedure: After preparing patient with proper cleaning and probing the tract, luke warm Nishadi Taila will be infiltrated into fistulous tract through the nozzle of syringe and it is dressed with a sterile guaze piece.
Dosage: 3 ml
Duration: Once daily for 28 days.

**Group B:**

Sample size: 20 patients.
Drug: *Gunavati Varti* externally and *Chiruvilwadi Kashaya* internally.
Procedure: After preparing patient with proper cleaning and probing, *Gunavati Varti* is taken and made luke warm. It will melt because the base of *Varti* is bee’s wax. Then it will be instilled into the fistulous tract through the nozzle of syringe and dressed with sterile gauze piece.

Dosage: 3 ml
Duration: Once daily for 28 days

**Follow-up:** The patients of both the group will be followed up for 3 months.

**4 ASSESEMENT CRITERIA:**

Assessment will be done on subjective and objective parameters before and after the treatment. Assessment is done on 0 day, 7th day, 14th day, 21st day, 28th day.

**Subjective parameters:**

a) Pain. – pain will be assessed by VAS

**Objective parameters**

a) Discharge – Discharge will be assessed by the soakage of gauze pad
b) Length of the tract. – length of the tract will be assessed by probing and measuring in centimeters
c) Healing index - Total length of tract healed divided by healing time in days, (will be measured in millimeters and will be filled in digits.)

**Investigations:**

1. Hb %.
2. BT, CT
3. ESR.
4. RBS
5. HBsAg, HIV.
7. MRI-Fistulogram (if necessary)
5. STATISTICAL METHODS
Statistical calculations will be done by ‘paired t test’, f test and anova test

3. Does the study require any investigations or interventions to be conducted on patients, healthy volunteers, cadaver or animal? If so, please describe briefly
Yes, Study require investigations and interventions in bhagandara patients using medicated drugs. But no healthy volunteers, cadaver or animals will be used in the study.

4. Has ethical clearance been obtained from your institution in case of (3)? YES (Human / animal)

5. LIST OF REFERENCES:-

9 Bailey & love’s Short practice of Surgery.  
Edited by- Russell(M.S. FRCS), Norman S Williams(FRCS),Christopher J.K. Bulstrode (FRCS), Arnold Hodder  Headline group ;London, 24th Edition 2004;  
Chapter no. 72- The Anus & Anal canal, Page no.- 1265 to 1268

10 S.Das – A Concise Textbook of Surgery. Published by Dr,S Das(F.R.C.S.); Kolkata  

11 Sahasra yogam edited by T.B.Pandita Rao, Sarada Nair, MahendraPal Singh  
Page No 27

☻☻☻
Name of the researcher/Scholar: NEELIMA SHERLY JOHN

Signature: 

Name and designation of the guide: Dr. RABINARAYAN TRIPATHY, M S (Ay)

Prof. & HOD, PG Department Of Shalyatantra

Remarks of the Guide: 

Signature with official seal: 

Name and designation of the Co-guide: Dr. SHAITHYA RAJ MS (Ay)

Lecturer, PG Department Of Shalyatantra

Signature with official seal: 

Name & designation of HOD: Dr. RABINARAYAN TRIPATHY MS (Ay)

Prof. & HOD, PG Department Of Shalyatantra

Signature with official seal: 

Name & designation of Head of Institution: Dr. M. R. VASUDEVAN NAMPOOTHIRI MD (Ay)

Principal, Amrita School Of Ayurveda

Signature with official seal: 

TOP
PROFORMA FOR REGISTRATION OF SYNOPSIS FOR DISSERTATION FOR
AYURVEDA DHANWANTARI (M.S Ay) IN SHALYATANTRA

“UNCONTROLLED SINGLE ARMED CLINICAL STUDY IN THE MANAGEMENT
OF FISSURE-IN-ANO BY DURVAADI KERA TAILA”

BY
SREEDEVI V

GUIDE
Prof. Dr. RABINARAYAN TRIPATHY. MS (Ay),

CO-GUIDE
Dr. SHAITHYA RAJ. MS (Ay),
LECTURER

DEPARTMENT OF PG STUDIES IN SHALYATHANTRA
AMRITA SCHOOL OF AYURVEDA
CLAPPANA P.O, VALLIKKAVU, KOLLAM
KERALA – 690525

Session - 2013-2014
From,

Dr. SREEDEVI V,
I year M. S. (Ay) Scholar,
Department of Post Graduate Studies in Shalyatantra
Amrita School of Ayurveda, Vallikkavu, Clappana P.O, Kollam, Kerala

To,

The Registrar,
Amrita Viswa Vidyapeetham, Ettimadai, Coimbatore, Tamilnadu

Through - The Principal & Head of Department of P.G. Studies in Shalyatantra,
Amrita School of Ayurveda, Vallikkavu, Clappana P.O, Kollam, Kerala.

Subject: Submission of Completed Proforma for Registration of Synopsis of Dissertation.

Respected Sir,

I request you to kindly register the below mentioned subject against my name for the submission of the dissertation to the Amrita Viswa Vidyapeetham, Ettimadai, Coimbatore as partial fulfillment of M.S. (Ay) in Shalyatantra.

THE TITLE OF DISSERTATION

“UNCONTROLLED SINGLE ARMED CLINICAL STUDY IN THE MANAGEMENT OF FISSURE-IN-ANO BY DURVAADI KERTA TAILA”

I am enclosing the completed Proforma for Registration of Subject of dissertation.

Thanking You,

Yours faithfully,

(Dr. SREEDEVI V)

Date: 28-05-2014
Place: Vallikkavu
1. **BRIEF RESUME OF THE INTENDED WORK**

   The major factors thought to influence the human susceptibility to diseases are diet and life style. The variations in these lead to altered bowel habit and diseases associated with it. Anal fissure is one such disease.

   Anal fissure is an elongated ulcer in the long axis of the lower anal canal\(^1\). It is described as an acute superficial break in the continuity of anoderm usually in the posterior midline of anal margin\(^2\). The common cause is trauma due to passage of hard stool followed by chronic infection\(^3\). Spasm of external anal sphincter is common and associated with local pain\(^4\). It affects all age groups with an equal incidence irrespective of sex\(^5\). Symptoms include sharp pain, hyper-sensitivity, tearing feeling in anus especially during bowel movement, fresh blood in stool and on wiping, visible tear and / or external skin tag at the lower end of fissure\(^6\).

   *Parikartika* is a similar condition explained in Ayurveda in which patient has excruciating cutting pain around anus\(^7\). Acharya Susruta documented it as *Virechana* and *Vasthi vyapat*\(^8\). Carakacharya described it as *Vasti-vyapat*, *Virechana-vyapat*, *Vasthinetra-vyapat*, complication of *Vatajaatisara* and due to excessive use of *Yapana vasthi*\(^9\). Acharya Vagbhata enumerated it under complication of *Vatajaatisara*\(^10\) and with reference to Kasyapa Samhita the disease is prevalently seen in gravid women\(^11\).

   Anal spasm results in severe pain, tearing of anoderm and decreased blood supply. The cycle of spasm, pain and ischemia contributes to the development of a chronic ulcer\(^12\). Keeping in view these factors, *Durvaadi taila*\(^13\) which is highly praised in the management of *Vrana* is proposed, after substituting the *Tila Taila* with coconut oil (*Kera Taila*), to study the efficacy in the management of fissure in ano. The present treatment modalities for fissure include lateral sphincterectomy, chemical sphincterectomy, topical anaesthetics, botulinum injections etc which has many untoward effects. So a simple method which is having better patient compliance is suggested in this study.

**I. NEED FOR THE STUDY:**

- Lateral internal sphincterectomy bears risk of anesthesia, peri-anal infection, hemorrhage, fecal incontinence, urinary retention. Flatus and fecal incontinence are the significant concerns which have been observed in as many as 35.7% cases\(^12\).
- Chemical sphincterectomy with nitrates generate headaches in 20-40% cases\(^12\).
- Botulinum toxin injection causes excessive weakness of anal sphincters and or injury to anal wall tissues. Transient incontinence to feces (5%) and flatus (18%), peri anal thrombosis and hematoma\(^12\).
• Search for cost effective and potent therapy to manage fissure in ano.
• Durvaadi Taila is an effective remedy for healing. The area of study is in Kollam district of Kerala where Kera Taila is easily available and widely used for therapeutic purpose, hence the Tila Taila was replaced with Kera taila to make it feasible to the patient.

All the above points suggest the necessity of opting a study for Clinical management of fissure using Durvaadi Kera Taila.

II. REVIEW OF LITERATURE:-

It includes an exhaustive screening through the Ancient Compendium, relevant contemporary text books of Ayurveda, Modern books of surgery, medicine, physiology, & pharmacology, Journals, magazines, seminars, conferences, digital library & web sites.

• Lakshanhas has been mentioned in Su.Chi.34/16, Ca.Si.6/62, Ca.Si.7/55
• Description of Durvaadi Taila from Sahasrayogam, Taila Kalpanas, modified preparation by substituting Tila Taila with Kera Taila.
• Fissure in ano from modern textbooks.

The list of previously done research work (dissertation) related to the present work are enlisted:

2. Kumar Sachin - Clinical Study on Parikartika with Karpooraadi Ghrita, SDM College of Ayurveda; RGUHS, Hassan; 2005.
III. **AIMS AND OBJECTIVES OF THE STUDY:-**

1. To study the effect of Durvaadi Kera Taila in anal fissure.
2. To study the clinical effect of Durvaadi Kera Taila in different signs and symptoms of anal fissure.
3. To derive a standard, easily accessible and cost effective therapy for the management of fissure in ano.

2. **MATERIALS AND METHODS:**

1. **SOURCES OF DATA:**

   The study is strictly confined to the cases of anal fissure, hence patients will be collected as per inclusion criteria from the Out Patient Department of Amrita Ayurveda Hospital, Vallikkavu, Kollam and other nearby hospitals and clinics. After careful scrutiny the patients will be registered under the present study.

2. **MATERIALS REQUIRED FOR THE STUDY:**

   The required materials are Durva and Kera Taila. The Durvaadi Kera taila will be prepared by Kera taila taken as its base. The swarasa and kalka of durva will be mixed to Kera taila as per classical method of taila paka vidhi.

**DRUG REVIEW:** The formulation contains the following ingredients:

<table>
<thead>
<tr>
<th>Name</th>
<th>Botanical Name /Family</th>
<th>Rasa</th>
<th>Guna</th>
<th>Veerya</th>
<th>Vipaka</th>
<th>Therapeutic Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Durva</td>
<td>Cynodon dactylon Poaceae</td>
<td>Kashaya, madhura</td>
<td>Laghu</td>
<td>Sita</td>
<td>Madhura</td>
<td>Vranyam, Dahaharam, kapha pitta hara Twak doshagna</td>
</tr>
<tr>
<td>Kera Tila</td>
<td>Cocos nucifera Arecaaceae</td>
<td>Madhura</td>
<td>Guru Snigdha</td>
<td>Sita</td>
<td>Madhura</td>
<td>Kshate hitam, Vajeekara, Dhatuposana Vata pitta hara</td>
</tr>
</tbody>
</table>

i) **METHODS OF COLLECTION OF DATA:**

1. **SAMPLE**

   Number of patients is 30 and is selected as per simple random sampling.
2. **INCLUSION CRITERIA:**
   
   iii) Patients in between 15 - 60 years of age, irrespective of sex.
   
   iv) Patients suffering from anal fissure with or without sentinel pile.
   
   v) Fissure at 6’O clock and 12’O clock positions.
   
   vi) Fissure with a history of more than 7 days of symptoms.
   
   vii) Patients with pain during defecation and with linear ulcer on inspection at the muco-cutaneous junction.
   
   viii) Patients complaining of severe burning sensation in anus after defecation.
   
   ix) Patients with complaints of streaks of blood over stools.

3. **EXCLUSION CRITERIA:**
   
   i) Patient less than 15 years of age and above 60 years.
   
   ii) Patients suffering from anal fissure with other ano-rectal diseases like piles, fistula, abscess etc.
   
   iii) Patients having anal carcinoma, papilloma, ulcerative colitis, Crohn’s disease, syphilitic fissure, tubercular ulcer & fistula.
   
   iv) Patients having other systemic pathology (TB, DM, HIV/AIDS, HBsAg, +ve & VDRL).
   
   v) Fissure at positions other than 6’O clock and 12’O clock.

**ii. PROCEDURE AND DESIGN OF STUDY**

The study will be a randomized control study in which 30 patients will be selected on the basis of simple random sampling (SRS) procedure. After proper Case taking, examination and investigations, data will be recorded in specially designed case sheets.

Raw drugs for the preparation of *Durvaadi Kera Taila* will be collected from the local available sources under the guidance of *Dravyaguna* Department of Amrita School of Ayurveda.

1. **MATERIALS AND METHODS**

Consent will be obtained from the patient / guardian for the study. For the selection of patients, to evaluate the morbidities and to assess the progress during and after treatment, investigations will be carried out in the Pathological laboratory attached to the hospital. *Taila* will be prepared in the pharmacy attached to the hospital under the guidance of faculties in *Bhaishajya Kalpana* and *Dravya guna* Department of Amrita School of Ayurveda.
2. DESIGN OF THE STUDY
The present study is an uncontrolled single arm clinical trial to manage the fissure in ano using Durvaadi Kera taila. Thirty patients diagnosed with fissure will be selected randomly and registered in the study.

3. GROUPING AND TREATMENT/PROCEDURE
All the 30 patients will be included under the present clinical trial procedure.

The patient will be in lithotomy position; manual anal dilatation up to two fingers will be done for two minutes after applying topical anaesthesia.

- **TRIAL GROUP**
  Sample size : 30 patients  
  Drug : Durvaadi Kera Tailam  
  Procedure : After cleaning of site, prepared trial drug will be administered through the anal canal using a 2ml disposable syringe  
  Dose : 2ml  
  Duration : Once daily for 7 days

  Patient will be asked to lie on the table for 15 minutes and during this time a pillow will be kept under the pelvic region. After the speculated observation time, a gauze pad will be given to avoid the spillage of oil.

A specially prepared chart for Ahara and Vihara will be given to all patients and hot Sitz bath will be advised 2 times, daily for 15 minutes. The treatment will be done for 7 days.

**FOLLOW UP** will be done on 14th day and 28th day.

4. ASSESSMENT CRITERIA: - Assessment will be done on subjective and objective parameters before and after treatment on 0 day & 7th day for the noting the efficacy of trial treatment, on 14th day and 28th day for recurrence study. The changes will be noted in the specially prepared case sheet.

**SUBJECTIVE PARAMETERS:**

- (i) Pain (MRC Grading / VAS of pain).
- (ii) Burning sensation
- (iii) Constipation.
- (iv) Sphincteric Spasm
- (iv) Discharge
- (v) Pruritus ani
OBJECTIVE PARAMETERS:

i) Healing of ulcer.

ii) Wound / Healing index = size of wound / time of healing in days.

INVESTIGATION REQUIRED: The necessary investigation if required will be done

8. Hb%
9. BT, CT
10. ESR
11. RBS
12. HBsAg, HIV
13. VDRL
14. Chest X RAY and MANTOUX TEST if Tuberculosis is suspected.

STATISTICAL METHODS

Statistical calculations will be done using Paired-T test

3. Does the study require any investigations or interventions to be conducted on Patients, Healthy Volunteers, Cadaver or animals? If so, please describe briefly:

Yes the study requires investigations and interventions on fissure-in-ano patients using medicated drugs. But no Healthy Volunteers, Cadaver or animals will be used in this study.

4. Has ethical clearance been obtained from your institution? YES

(Human / animal)

5. LIST OF REFERENCES:-


10. Acharya Vrudha Vagbhata, ASHTANGA HRUDAYA, with commentaries of Aruna Dutta (Sarvanga Sundara) and Hemadri(Ayurveda Rasayana), Chaukhambha Sanskrit Santhan, Varanasi, Reprint Edition-2012, Ni.7th/6, page 496.


**********
Name of the Researcher/Scholar: SREEDEVI V
Signature:

Name & Designation of Guide: Dr. RABINARAYAN TRIPATHY MS(Ay)
Professor.
P.G. Dept. of Shalyatantra.
Remarks of the Guide:

Signature with Official Seal:

Name & designation of Co-Guide: Dr. SHAITHYA RAJ M.S(Ay)
Lecturer,
P.G. Dept. of Shalyatantra.

Signature with Official Seal:

Name & designation of Head of Department: Dr. RABINARAYAN TRIPATHY M.S. (Ay)
Prof. & H.O.D, P.G. Dept. of Shalyatantra.

Signatures with official seal:

Name & designation of Head of Institution: Dr. M.R. VASUDEVAN NAMPOOTHIRI M.D (AY)
Principal, Amrita School of Ayurveda.

Signatures with official seal:

************

TOP
AMRITA SCHOOL OF AYURVEDA  
AMRITA VISWAVIDYAPEETHAM  
(University under sec.3 UGC Act 1956)

PROFORMA FOR REGISTRATION OF SUBJECT FOR DISSERTATION FOR  
AYURVEDA VACHASPATI M.S(Ay) IN SHALYATANTRA 

“OPEN LABEL CASE CONTROLLED CLINICAL STUDY TO EVALUATE THE  
eFFECTIVENESS OF NYAGRODHADI GANA IN BHAGNA SANDHAANA.”

BY 
P. SURESH 

GUIDE  
Prof. Dr. G.S. RAJU, MD(Ay) 

CO-GUIDE  
Prof. Dr. RABINARAYAN TRIPATHY, MS (Ay),

DEPARTMENT OF POST GRADUATE STUDIES IN SHALYATANTRA  
AMRITA SCHOOL OF AYURVEDA, VALLIKKAVU, CLAPPANA P O,  
KOLLAM, KERALA  

SESSION - 2013-2014
From

P.SURESH
I Year M. S. (Ay) Scholar,
Department of Post Graduate Studies in ShalyaTantra,
Amrita School of Ayurveda
Vallikkavu, Clappana. Kollam, Kerala - 690525.

To

The Registrar, Amrita Viswavidyapeetham, Coimbatore, Tamilnadu.

Through, - The Principal & Head of Department of P.G. studies in Shalya-Tantra, Amrita School Of Ayurveda, Vallikkavu, Clappana. Kollam, Kerala

Subject: Submission of Completed Proforma for Registration of Synopsis of Dissertation.

Respected Sir,

I request you to kindly register the below mentioned subject against my name for the submission of the dissertation to the Amrita Viswa vidyapeetham, Coimbatore , Tamilnadu, as partial fulfillment of M.S. (Ay) in Shalya-Tantra.

THE TITLE OF DISSERTATION:
“OPEN LABEL CASE CONTROLLED CLINICAL STUDY TO EVALUATE THE EFFECTIVENESS OF NYAGRODHADI GANA IN BHAGNA SANDHAANA.”

I am enclosing completed proforma for Registration of Subject of dissertation.

Thanking you.

Yours faithfully

(Dr. P.Suresh)

Place: Vallikkavu

Date: 25-04-2014
1. BRIEF RESUME OF THE INTENDED WORK:

Trauma is a major problem worldwide, due to widespread industrialization and use of vehicles, where incidence of accidents resulting in fracture and soft tissue injury is higher.

A fracture is a complete or incomplete break in the continuity of a bone or a crack. Ayurvedic texts have illustrated fracture as being the loss in the continuity of the bone due to pressure. Fractures commonly result following injuries. However, the incidence of the long bone fracture is higher and thus, demands special attention. The management of long bone fracture runs through the basic principle of fracture management viz. 1. Reduction, 2. Retention and 3. Rehabilitation. Even after following basic principles, sometimes the fractures may not heal properly and leads to complications like non-union, mal-union, avascular necrosis, shortening of limbs etc.

According to the modern principles of management, fracture is reduced, immobilized and then, the role of medicine is negligible. Only some NSAID, Calcium supplements etc. are given to meet the symptomatic demand. But in ancient treatise so many indigenous compounds are mentioned which can promote the healing of fracture. With reference to Ashtanga Hrudaya, an indigenous compound named as Nyagrodhadi gana is also praised for bhagna sandhaana, ie fracture healing. Hence the present study was proposed to find out the effect of Nyagrodhadi gana on healing of fracture.

I. NEED FOR THE STUDY:

* The incidence of hospital occupancy due to fractures is very high and almost always incapacitating the individuals, bringing about a sudden stoppage of their daily activities, hindering their routine work, more severely affecting the elderly and have tremendous impact on both the health system and society in general.

* In delayed healing, no proper medicine is prescribed in modern medicine. To reduce long term hospitalization and to make cost effective treatment with easily available drug, the present study is designed.

* While considering various factors and complications in fracture healing, it is essential to assess the different mode of actions of number of Ayurvedic drugs insisted by various Sages in the acceleration of fracture healing.

* Nyagrodhadi Gana described in Ashtanga Hrudaya Sutrasthana can be used as internal medication for ‘bhagna sandhaana’. Keeping in view the above factors, to
evaluate the efficacy of Nyagrodhadi gana on simple fractures, the present study is proposed.

II. REVIEW OF LITERATURE:

- In Susrutha Samhitha Nidana sthana 15th chapter, Acharya describes about different nidanas which leads to injury as well as different types of fractures and dislocation\(^6\). Specific symptoms are clearly detailed in this chapter. In Chikitsa Sthana 3rd chapter the treatments are well explained.\(^7\)

**Previous research done:**

- Sanjeev Tiwary: Clinical Management of Urvasthi Griva Bhagna with Gandha taila, NKJAMC Bidar, RGUHS -2007

III. AIM AND OBJECTIVE OF THE STUDY:

- To study effect of Nyagrodhadi gana in bhagna sandhaana.
- To evaluate the efficacy of Nyagrodhadi gana on callus formation.
- To evaluate the efficacy of Nyagrodhadi gana on serum calcium.

2. MATERIALS AND METHODS:

I. SOURCE OF DATA:

i) Patients with simple long bone fractures will be selected from the Amrita School of Ayurveda Hospital, Clappana, Kollam.

ii) Samhita, modern books of Surgery, Medicine, Physiology, & Pharmacology.

iii) Journals, Magazines, Seminars, Conferences, Digital library & Web sites.

iv) Pathological laboratory attached to the hospital.
II. MATERIALS REQUIRED FOR THE STUDY:

Nyagrodhadi gana will be prepared as per the classical reference as mentioned in Sharangadhar Shamhita under the supervision of Bhaishajya kalpana and Dravya guna Department s of Amrita School of Ayurveda.

<table>
<thead>
<tr>
<th>San. Name</th>
<th>Bot. Name</th>
<th>Family</th>
<th>Rasa</th>
<th>Guna</th>
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<tbody>
<tr>
<td>Nyagrodha</td>
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</table>
i) METHOD OF COLLECTION OF DATA:

1. **Sample:** It is a clinical study in which 40 patients will be selected on the basis of simple random sampling (SRS) procedure.

2. **Inclusion Criteria:**
   1. Patients between 25-60 year, irrespective of sex.
   2. Patients with simple fractures.
   3. Fracture with history of trauma.
   4. Fracture diagnosed by radiograph.

3. **Exclusion Criteria:**
   1. Patients aged below 25 years and above 60 years.
   2. Patients having other systemic pathology (TB, Osteoporosis, etc..)
   3. Multiple, Compound or Comminuted fracture.

**PROCEDURE AND DESIGN OF THE STUDY**

The study is an open clinical study in which 40 patients will be selected on the basis of simple random sampling (SRS) procedure & will be divided in 2 equal groups. Consent will be obtained from the patients who are registered for the trial.
1. MATERIALS AND METHODS:
   1. POP bandage rolls, Cotton, Guaze – as required.
   2. The raw drugs of Nyagrodhadi gana.

Design of The Study:
Patients will be clinically examined thoroughly and radiograph will be used for diagnosis. After confirmation, patients will be registered in the OPD of the College hospital and will be divided in 2 equal groups.

Grouping and treatment / Procedure:

- **G1- Trial group:** - Patients will be given Nyagrodhadi gana in Kwatha form 50 ML twice daily.
- **G2 - Control group:** - Patients will be treated by the basic principle of fracture management.

Initially all the patients will be treated with reduction and immobilization. During treatment, the patients will be regularly observed. The changes will be noted in the specially prepared case sheet. The observations will be analyzed on the basis of assessment parameters (both subjective & objective) critically & scientifically; before, during & after treatment on 0th, 15th, 30th & 45th day. Finally the result will be statistically evaluated for its significance.

Assessment Criteria:

The clinical assessment will be done with the initial finding through clinical, Pathological and radiological statements & compared with the result of changes on 15th, 30th, & 45th day.

1. Pain: assessed by medical research council grading of pain & by VAS (visual analog scale).
2. Swelling: By measuring the circumference in cm and comparing with the normal limb.
3. Tenderness: Elicited by the back of the thumb on first day, On 15th, 30th & 45th day by springing Test.
4. Loss of function.
5. Shortening: By comparing with the normal limb.
6. Test of Union: Mobility between fragments & Pain with angulations’ stress.
Investigations:
- DC, TLC, Hb%
- HIV, HbsAg
- Serum Calcium
- ESR
- Blood Sugar
- X – Ray

Statistical Methods: Statistical calculations will be done to find out the significance by ‘Paired T test’ & Annova test.

3. Does the study require any investigations or interventions to be conducted on Patients, Healthy volunteers, cadaver or animals? If so, please describe briefly:
   Study will be conducted on the patients with simple fracture only. No animal experiments will be conducted.

4. Has ethical clearance been obtained from your institution in case of (3) ? YES

LIST OF REFERENCES:
2. S. Das – A Practical Guide to Operative Surgery Published by Dr. S Das (F.R.C.S.); Kolkata; 5th edition, 2007, chapter 9, Page no. 99-105
4. Dr. J. Maheshwary, Essential Orthopedics, Jaypee Brothers Medical Publisher’e (p) Ltd, New Delhi, Fourth edition 2011, Chapter 1, page no. 13.
Name of the researcher/ Scholar : SURESH.P

Signature :

Name and designation of the guide : Dr.G.S.RAJU, MD(Ay);
Professor, PG Department of Shalyatantra

Remarks of the Guide :

Signatures with official seal :

Name and designation of the Co-guide : Dr. RABINARAYAN TRIPATHY, M S (Ay)
Prof. & HOD, PG Department of Shalyatantra.

Signatures with official seal :

Name and designation of Head of Dept. : Dr. RABINARAYAN TRIPATHY. MS (Ay)
Prof. & HOD, PG Department of Shalyatantra.

Signatures with official seal :

Name and designation of Head of Institution : Dr. M.R. VASUDEVAN NAMPOOTHIRI. MD(Ay)
Principal, Amrita School of Ayurveda.

TOP